

REMARKS

By way of this Response, Applicant re-asserts and incorporates by reference its prior arguments before the Office, including those arguments made in the responses submitted on April 29, 2004; December 15, 2006; July 30, 2007; February 21, 2008; July 29, 2008 and January 21, 2009.

I. Summary of the Final Office Action Mailed April 16, 2009

In the Final Office Action mailed April 16, 2009, the Examiner withdrew the previous objection to the drawings. The Examiner rejected Claim 1 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Claim 1 was also rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to specifically point out and distinctly claim the subject matter regarded as the invention. The Examiner also maintained the rejection of Claims 1-10 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,716,638 (Touitou) in view of U.S. Patent No. 6,509,005 (Peart) and “*Airways Response to Aerosolized Delta-9-Tetrahydrocannabinol: Preliminary Report*” by Vachon *et al.* (Vachon). In addition, the Examiner maintained the rejection of Claims 9 and 10 under 35 U.S.C. § 103(a) as being unpatentable over Touitou in view of Peart and Vachon, and further in view of U.S. Patent No. 5,258,336 (LaMastro).

II. Status of the Claims

Claims 1-10 were pending. By way of this Response, Claims 1 and 6 have been amended. Applicant respectfully submits that no new matter is presented by way of this Response. Support for the amendments can be found at least at paragraphs 51-53 and 56 of the published application. Applicant makes these amendments solely to expedite the prosecution of the present application and does so without admitting or conceding, in any manner, the appropriateness of any rejection.

III. The Rejections Under 35 U.S.C. § 112 Should be Withdrawn

The Examiner rejected Claim 1 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Specifically, the Examiner found that the specification did not support a composition which is “substantially free” of a phospholipid. The Examiner also rejected Claim 1 under 35 U.S.C. § 112, second paragraph, as indefinite, finding the specification did not indicate the minimum amount of phospholipid which could be added in view of the “substantially free” limitation.

Applicant has amended Claim 1 by replacing the limitation of “substantially free” with “free.” Paragraphs 51 to 53 of the application as published, disclose the components of the solvent, and disclose that a phospholipid is not present. Accordingly, Applicant respectfully submits that the requirements of 35 U.S.C. § 112 have been met. Based on the following amendment, Applicant respectfully requests that the Examiner withdraw the rejection under 35 U.S.C. § 112.

IV. The Rejections Under 35 U.S.C. § 103(a) Should be Withdrawn

A. Claims 1-10 are not obvious over Touitou in view of Peart and Vachon

The Examiner maintained the rejection of Claims 1-10 as obvious over Touitou in view of Peart and Vachon. Applicant respectfully submits that the presently pending claims are in condition for allowance.

The burden of establishing a *prima facie* case of obviousness lies with the Examiner. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be an apparent reason why a person of ordinary skill would have combined the prior art elements in the manner claimed. Second, there must be a reasonable expectation of success. Third, the references, when combined, must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the cited references and not in an applicant’s disclosure. *See* M.P.E.P. § 2143.

However, in order to combine references to form the basis of an obviousness rejection, it is “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way that the claimed new invention does.” *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Although after *KSR* the teaching, suggestion and motivation requirement is no longer *sine qua non* of obviousness, a claim is “not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 1741. Moreover, the Court’s holding in *KSR* did not “mention or effect the requirement that each and every claim limitation be found present in the combination of the prior art references before any analysis proceeds.” *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 846, 852 (N.D. Ill. 2007), *aff’d* *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008).

Touitou, either alone or in combination with Peart and Vachon, fails to teach or suggest all the elements of the pending claims. Touitou discloses a cosmetic or medical composition containing an active ingredient for topical administration. (Touitou at abstract.) The topical

delivery system disclosed therein contains phospholipids, short chain alcohols and water. (Touitou 1:8-11.) The delivery system may also comprise a glycol. (*Id.*) Touitou relies entirely on the phospholipid to solubilize the tetrahydrocannabinol by utilizing the phospholipid to create an ethosomal emulsion incorporating the tetrahydrocannabinol. (*Id.* 1:41-43.)

As a result of its reliance on the phospholipid to solubilize the tetrahydrocannabinol, Touitou fails to teach or suggest all of the limitations of the pending claims. Upon reading Touitou, one skilled in the art would consider the presence of a phospholipid essential to the solubility of the active ingredient and maintenance of a suitable composition. Thus, the skilled artisan, in reading Touitou would not find it obvious to prepare an aerosolizable tetrahydrocannabinol composition without a phospholipid to solublize the active ingredient. In contrast, amended Claim 1 clarifies that the solvent is free of a phospholipid.

The teachings of Peart fail to remedy the deficiencies of Touitou. Peart discloses an aerosol propellant system for tetrahydrocannabinol that does not require the presence of a solvent. (Peart at 5:50-55.) Peart further teaches that if a solvent, such as ethanol is used, it should comprise less than 20%, and most preferably, less than 15% of the system. (Peart at 5:52-55.) Moreover, Peart teaches that the use of ethanol concentrations in excess of about 20% will result in a particle size too large to effectively administer tetrahydrocannabinol to the lungs. (Peart at 5:28-32.) The Examiner contended that Peart continued to read on the amendment of “about 20%” alcohol, because “about” is a relative term that can included amounts less than 20%. Applicant submits that a skilled artisan would not understand “about 20%” to read on the teachings of Peart. As such, Peart fails to read on the pending claims.

Further, the Examiner has put forth no new arguments in support of the rejection based on Vachon. Accordingly, Applicant re-asserts its prior arguments regarding the inapplicability of Vachon to the pending claims.

Based on the foregoing, Applicant respectfully submits that independent Claim 1 is not obvious over Touitou in view of Peart and Vachon. Claims 2-10 depend from independent Claim 1. As such, the patentability of amended Claim 1 over the prior art establishes the patentability of Claims 2-10. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) based on Touitou in view of Peart and Vachon be withdrawn.

B. Claims 9 and 10 are not obvious over Touitou in view of Peart, Vachon and LaMastro

The Examiner rejected Claims 9 and 10 as obvious over Touitou in view of Peart, Vachon and LaMastro. Based on the remarks above, Touitou in view of Peart and Vachon fails to teach or suggest all the elements of Claim 1 as amended. LaMastro fails to remedy the shortcomings of these references. The Examiner has put forth no new arguments in support of the rejection based on LaMastro. Accordingly, Applicant re-asserts its prior arguments regarding the inapplicability of LaMastro to the pending claims. Claims 9 and 10 depend from independent Claim 1. As such, the patentability of independent Claim 1, as amended, over the prior art establishes the patentability of Claims 9 and 10. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) based on Touitou in view of Peart, Vachon and LaMastro be withdrawn.

V. Conclusion

Applicant believes that all of the pending claims are now in condition for allowance and respectfully requests notice to that effect. Should the Examiner wish to discuss the case, the Examiner is invited to call the undersigned at 312-701-8115.

Respectfully submitted,

By: Vera A. Nackovic
Vera A. Nackovic
Reg. No. 59,388

CUSTOMER NUMBER 26565
MAYER BROWN LLP
P.O. Box 2828
Chicago, Illinois 60690-2828
Telephone: (312) 701-8115
Facsimile: (312) 706-9000